

## REMARKS

The final Office Action of July 27, 2011, has been received and reviewed.

Claims 1, 2, 7-16 and 18-23 were previously pending and under consideration in the above-reference application. Each of claims 1, 2 17-16 and 18-23 has been rejected.

Reconsideration of the above-referenced application is respectfully solicited.

### Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1, 2, 7-16 and 18-23 have been rejected under written description requirement of the first paragraph of 35 U.S.C. § 112.

With respect to the enablement requirement of the first paragraph of 35 U.S.C. § 112, M.P.E.P. § 2164.01 provides:

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention.

There is no *in haec verba* requirement (M.P.E.P. § 2163); the exact language recited in the claims need not be found verbatim in the originally-filed specification to be supported by the originally-filed specification. M.P.E.P. § 2173.05(f) (which applies to 35 U.S.C. § 112, second paragraph, indefiniteness rejections, provides “[t]here is no requirement that the words in the claim must match those used in the specification disclosure.”).

The Office has objected to use of the phrase “an antigen that corresponds to at least one pathogen to which the source animal is not normally exposed” in independent claim 1 and to the phrase “at least one antigenic agent not normally present in an environment in which the source animal lives” in independent claim 20.

It is respectfully submitted that as-filed specification provides an adequate written description of the subject matter recited by both independent claim 1 and independent claim 20. In particular, paragraph [0027] indicates that “non-specific transfer factor” is produced in response to pathogens “that are present in [an] animal’s natural environment.” In contrast, as

paragraph [0028] strongly suggests, “antigen-specific transfer factor” may be obtained by exposing an animal to “specific antigenic agents” (*see* paragraph [0041]) that are not present in the animal’s natural environment. That is because an animal already makes transfer factor for antigenic agents that are present in its natural environment, and one of ordinary skill in the art therefore wouldn’t expect that further exposure of the animal to such an antigenic agent would cause the animal to produce a new type of transfer factor. Thus, one of ordinary skill in the art wouldn’t consider an antigenic agent that is already present in an animal’s natural environment to be a “specific antigenic agent,” as that term is defined by the as-filed disclosure.

Despite the lack of an *in haec verba* requirement, the language to which the Office objects has been removed from independent claims 1 and 20, and has been replaced with the phrase “specific antigenic agent.” The as-filed disclosure clearly provides an adequate written description of the “specific antigenic agent[s]” recited by independent claims 1 and 20, and indicates that a “specific antigenic agent” is an antigenic agent to which a source animal is not normally (in its natural environment) exposed.

In view of the foregoing, it is respectfully submitted that independent claims 1 and 20 comply with the written description requirement of the first paragraph of 35 U.S.C. § 112.

#### Claims

It is further submitted that the revisions of independent claims 1 and 20 do not narrow the scope of either of these claims, or of any of their dependent claims. Claims 2, 7-12, 14-16 and 18 are allowable, among other reasons, for depending from independent claim 1, which is allowable. Claim 13 has been canceled without prejudice or disclaimer, rendering its rejection moot. Claims 21-23 are allowable, among other reasons, for depending from independent claim 20, which is allowable. Accordingly, withdrawal of the 35 U.S.C. § 112, first paragraph, written description rejections of claims 1, 2, 7-16 and 18-23 is respectfully solicited, as is the allowance of each of claims 1, 2, 7-12, 14-16 and 18-23.

**Rejections under 35 U.S.C. § 112, Second Paragraph**

Claims 1, 2, 7-16 and 18-23 stand rejected under 35 U.S.C. §112, second paragraph, for being drawn to subject matter that is purportedly indefinite.

The rejections under 35 U.S.C. § 112, second paragraph, are based on similar rationale to the 35 U.S.C. § 112, first paragraph, written description rejections. Claims 1, 2, 7-12, 14-16 and 18-23 are allowable because, as explained previously herein, one of ordinary skill in the art would understand the scope and meaning of each of these claims from the description provided in the as-filed disclosure. Thus, each of claims 1, 2, 7-12, 14-16 and 18-23 complies with the definiteness requirement of the second paragraph of 35 U.S.C. § 112.

Claim 13 has been canceled without prejudice or disclaimer.

For these reasons, withdrawal of the 35 U.S.C. § 112, second paragraph, rejections of claims 1, 2, 7-16 and 18-23 is respectfully solicited, as is the allowance of each of claims 1, 2, 7-12, 14-16 and 18-23.

**Rejection under 35 U.S.C. § 112, Fourth Paragraph**

Claim 13 has been rejected under 35 U.S.C. §112, fourth paragraph, for failing to further limit the subject matter of the claim from which it depends.

Claim 13 has been canceled without prejudice or disclaimer, rendering the rejection of that claim moot.

**Rejections under 35 U.S.C. § 102(e)**

The Office has rejected claims 1, 2, 7-16 and 18-22 under 35 U.S.C. § 102(e) for being directed to subject matter that is purportedly anticipated by the subject matter described in U.S. Patent Application Publication 2002/0044942A1 of Dopson (hereinafter “Dopson”).

The Office’s indication that the 35 U.S.C. § 102(e) rejection based on Dopson may be overcome by filing an affidavit in accordance with the requirements 37 C.F.R. § 1.131 is gratefully acknowledged. Such an affidavit will be prepared and executed when all further issues in the above-referenced application have been resolved.

### Rejections under 35 U.S.C. § 103(a)

Claims 1, 2, 7-16 and 18-22 have also been rejected under 35 U.S.C. § 103(a) for being drawn to subject matter that is purportedly unpatentable over the subject matter taught by U.S. Patent 5,080,895 to Tokoro (hereinafter “Tokoro”), in view of teachings from U.S. Patent 5,840,700 to Kirkpatrick (hereinafter “Kirkpatrick”).

There are several requirements for establishing a *prima facie* case of obviousness against the claims of a patent application. All of the limitations of the claim must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Even then, a claim “is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007). The Office must also establish that one of ordinary skill in the art would have been able to predict that the purported modification or combination of reference teachings would have been successful. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). In order to demonstrate such predictability, the Office must articulate some “reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.*, quoting *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006). That reason must be found in the prior art, common knowledge, or derived from the nature of the problem itself, and not based on the Applicant’s disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006). A mere conclusory statement that one of ordinary skill in the art would have been motivated to combine or modify reference teachings will not suffice. *KSR* at 1396.

Independent claims 1 and 20 are both directed to methods for causing treated animals to elicit T cell mediated immune responses. These methods include administering an extract of an egg to a treated animal. The extract, which consists of egg yolk, includes transfer factor. The transfer factor is specific for at least one pathogen that is not normally present in an environment in which the source animal lives.

The teachings of Tokoro relate to a “transfer factor-like component” generated by chickens in response to three “specific antigen agent[s].” As has already been established, none

of the three specific antigenic agents identified by Tokoro actually causes a chicken to produce transfer factor that ends up in the chicken's eggs.

Although Tokoro provides a lengthy list of other antigenic agents that may cause a source animal, specifically a chicken, to produce a transfer factor-like component, Tokoro does not provide any indication that any of the listed antigenic agents meets the requirements of amended independent claim 1 or the requirements of amended independent claim 20; *i.e.*, that: the antigens comprise at least one "specific antigenic agent;" and that transfer factor produced by the source animal be specific for that at least one specific antigenic agent. Nor does any of the art that has been cited by the Office suggest that a composition that includes transfer factor specific for at least one specific antigenic agent may be administered to another type of animal.

The teachings of Kirkpatrick relate to techniques for isolating transfer factors with certain specificities. Kirkpatrick lacks any teaching or suggestion that transfer factor may be obtained from an egg of a source animal. In addition, like Tokoro, Kirkpatrick provides no teaching or suggestion of a method in which an egg extract that includes transfer factor specific for at least one specific antigenic agent may actually be administered to another type of animal.

For these reasons, it is respectfully submitted that the art that has been relied upon by the Office in rejecting independent claims 1 and 20 does not provide any basis for predicting the subject matter recited by either of these claims, as amended. Thus, a *prima facie* case of obviousness has not been established against either of these claims or against any of their dependent claims.

Accordingly, it is respectfully submitted that, under 35 U.S.C. § 103(a), each of claims 1, 2, 7-12, 14-16 and 18-22 is drawn to subject matter that is allowable over teachings from Tokoro and Kirkpatrick. Claim 13 has been canceled without prejudice or disclaimer. Withdrawal of the 35 U.S.C. § 103(a) rejections of claims 1, 2, 7-16 and 18-22 is, therefore, respectfully solicited, as is the allowance of each of claims 1, 2, 7-12, 14-16 and 18-22.

## CONCLUSION

It is respectfully submitted that each of claims 1, 2, 7-12, 14-16 and 18-23 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully Submitted,

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